

Morgan Lewis



Emerging Life Sciences Companies

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Chapter 7

Freedom to Operate

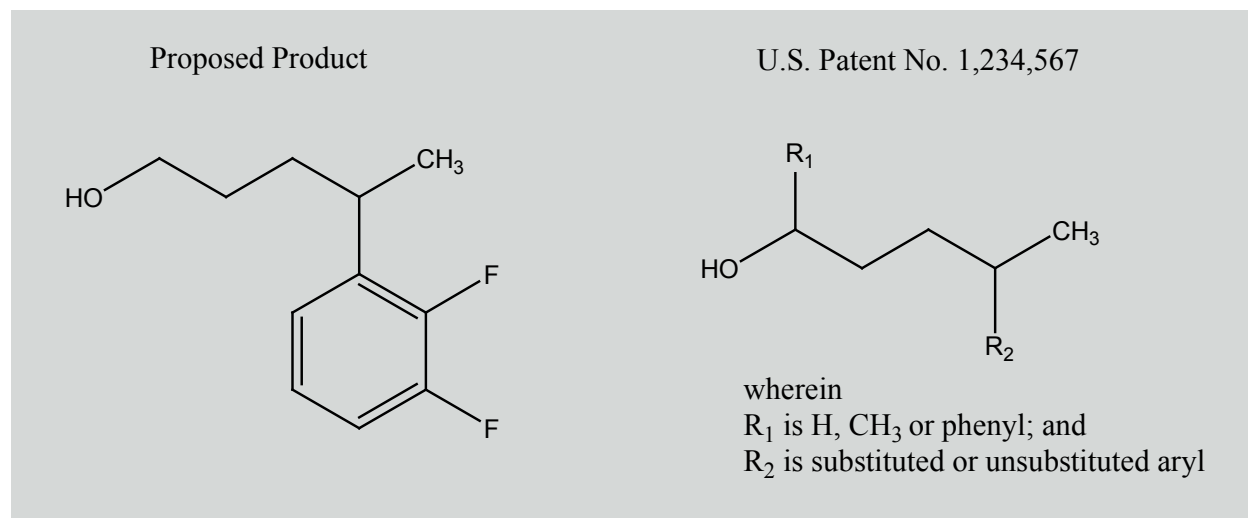
Chapter 7

FREEDOM TO OPERATE

As life sciences companies develop their patent portfolios, they come to realize that being able to patent their inventions is only the beginning. They must also be able to use their inventions to make and sell products. A patent grants an inventor the right to exclude others from making, using, or selling a claimed invention. As noted in Chapter 6, however, this does not give the inventor the right to make, use, or sell the claimed invention—in other words, having a patent does not guarantee that the patentee can exploit it, as third parties may have patent coverage that dominates the patentee's position.

It is important to note that the claims of a patent are what determine what can or cannot be made, used, or sold. Within the life sciences industry, a particularly common mistake in evaluating a competitor's IP portfolio is to focus on what the patentee did (e.g., what actual science was performed). This can lead to a number of problems because it is not what the patentee does that counts but what it claims in its patent.

A few simplistic analogies are appropriate. A chemical example is depicted below.



In the above example, because the proposed product includes H at the R₁ location and a substituted aryl at the R₂ location, the proposed product falls within the scope of claim 1. Accordingly, the proposed product would infringe the '567 patent without a license.

Let's also consider a biologics example: Company A has cloned NewGene. Company A gets a patent with claims to nucleic acids containing at least 20 base pairs of the novel DNA sequence

and anything that is 95% identical to NewGene. Company B figures out that there are particularly important single nucleotide polymorphisms (SNPs) within the gene, the detection of which leads to differential treatment. Company B patents a number of primer and probe sequences (some of which are 20 or more base pairs in length) that are useful in kits. However, Company B cannot sell these kits, as Company A's patent dominates.

An additional example worth noting is in the area of combination patents. Company C has a patent to Drug X, useful as a chemotherapeutic. Company D wants to sell Drug X in combination with its own Drug Y, useful for the treatment of hair loss. Company D needs a license from Company C in order to do so.

Thus, the patentability of an invention is different from the ability to practice it, the latter of which is generally referred to as “freedom to operate.”

What Is Freedom to Operate?

Freedom to operate (FTO) is the ability of your Company to develop, make, and market products without legal liabilities to third parties (e.g., other patent holders). A truly determinative FTO finding only comes under two circumstances. In one instance, a company licenses the patent, in which case such company knows it will not be sued for infringement short of a breach of the contract. In the other, final FTO status comes after adjudication, in which a court finds either no infringement of the third-party patent or that the third-party patent is invalid. In some cases, a company will rely on both reasons (e.g., the company may rely on noninfringement of some claims of a patent and invalidity of other claims). Examples of infringement and invalidity analyses are provided later in this chapter.

Freedom to Operate Analyses

Infringement Analyses

The United States Code states:

Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.¹

Infringement in this context can occur in several ways. “Literal infringement” means that the proposed product literally infringes the claim as drafted. This is in comparison to infringement under the “doctrine of equivalents,” which is a judicially created doctrine that attaches infringement liability in the absence of literal infringement even though the infringing device or process does not fall within the literal scope of a patent claim, but nevertheless is equivalent to the claimed invention.

1. 35 U.S.C. § 271.

In addition, infringement can be “direct,” “contributory,” or “induced.” A person directly infringes a patent by making, using, offering to sell, selling, or importing into the United States any patented invention, without authority, during the term of the patent. Indirect infringement can occur, for instance, when a device is claimed in a patent and when a third party supplies a product that can only be reasonably used to make the claimed device. In the United States, indirect infringement includes “contributory” or “induced” infringement.

Contributory infringement is defined as follows:

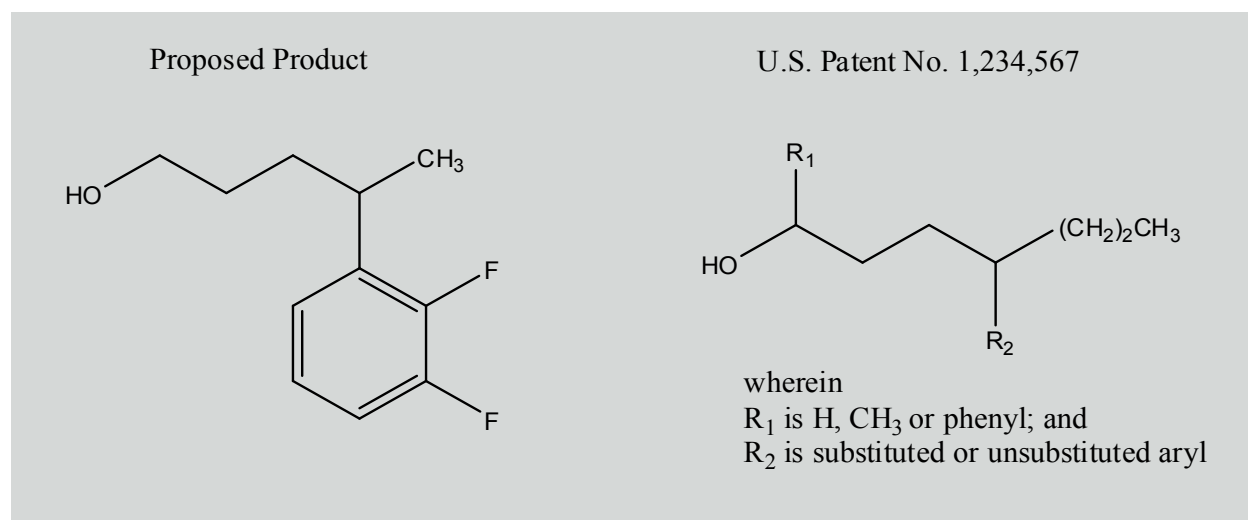
Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.²

Induced (active) infringement is defined by the U.S. Code as “[w]hoever actively induces infringement of a patent.”³

The following examples deal with direct, literal infringement.

The first step in such an analysis is to determine whether the proposed product(s) or method(s) infringe the third-party patents. A few visual examples are presented to explain the general concepts—in each case, the infringing compound must have a claimed feature of the patented compound. Each example that follows underscores the importance of understanding the claim terms.

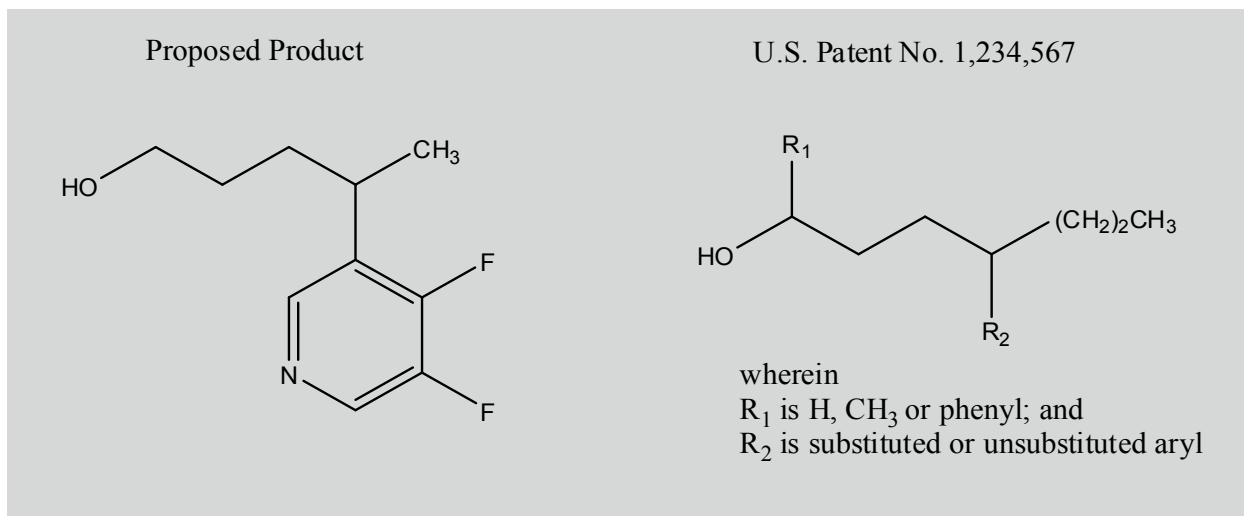
In this example, the proposed product does not literally infringe the ’567 patent due to the difference in the methyl and propyl groups:



2. *Id.* § 271(c).

3. *Id.* § 271(b).

A second example shows that the definition of the claim term could be determinative:



In this example, does the term “aryl” include the fused heteroaryl at R₂? This requires an analysis of the term “aryl,” taking into account the description and/or definition in the specification of the patent, the file history of the patent, dictionary definitions, and the like. If the term “aryl” is distinct from the term “heteroaryl,” then infringement is unlikely.

In the three biological examples below, infringement liability is likely in Examples 1 and 3. There is no literal infringement in Example 2.

Proposed Product

Met-Val-Tyr-Ile-Pro-Ser-Ala-Gly-Gln-Leu-PEG

U.S. Patent No. 1,234,567

Example 1

A PEGylated peptide comprising the sequence Val-Tyr-Ile-Pro-Ser-Ala

Example 2

A PEGylated peptide comprising the sequence Met-Val-Tyr-Ile-Pro-Ser-Ala-Gly-Gln-Leu

Example 3

A PEGylated peptide at least 90% identical to the sequence Met-Val-Tyr-Ile-Pro-Ser-Ala-Gly-Gln-Leu

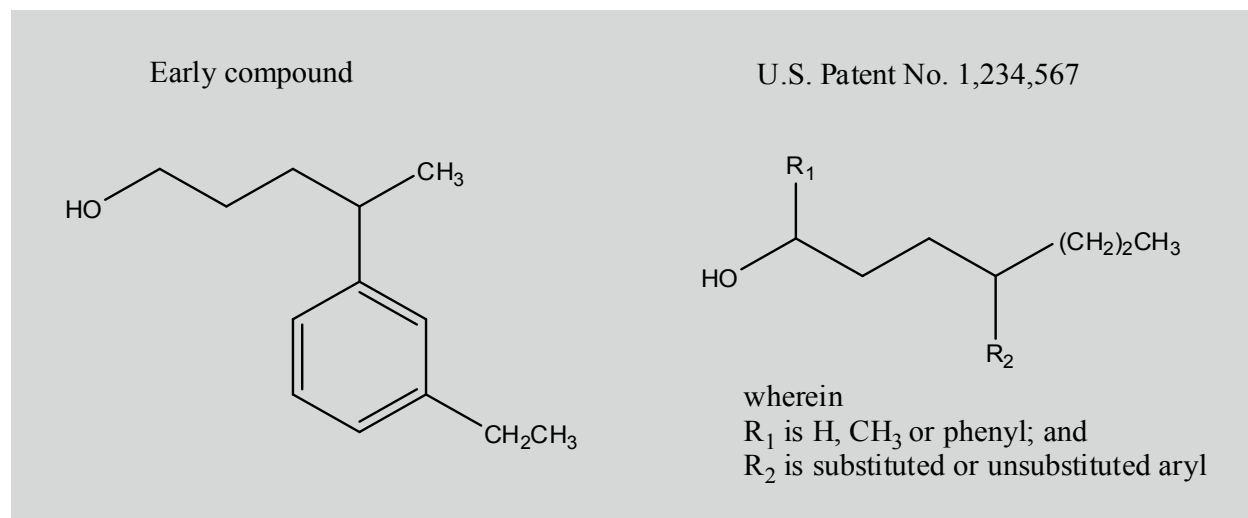
Invalidity Analyses

Invalidity of a claim requires that the claim not meet at least one of the statutory requirements of a patent—namely, that the invention is patentable, novel, and nonobvious—and that the specification meets the requirements of 35 U.S.C. § 112 (including definiteness, written descriptions, enablement, and best mode). The examples below are relatively straightforward, and thus not necessarily exemplary.

Invalidity Based on Novelty: Anticipation

An invalidity analysis begins with a structured search for one or more references that were publicly available prior to the priority date of the patent.

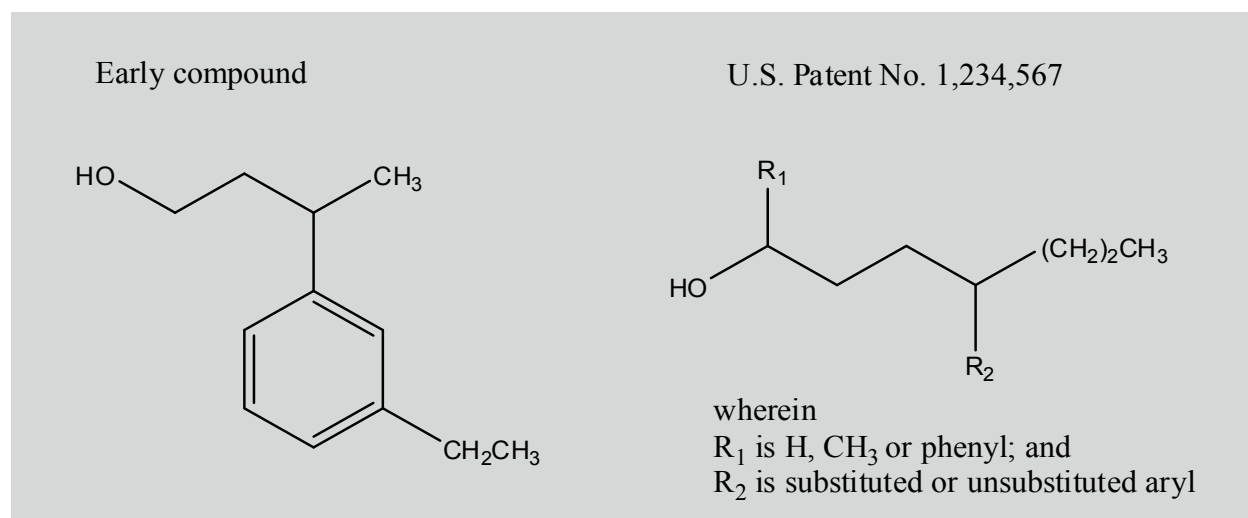
For example, a paper, authored by Early et al., appeared in the *Golden State Journal of Chemistry* on January 1, 1988.



The priority date for the application that matured into U.S. Patent No. 1,234,567 is March 15, 1989. Since Early et al. disclosed a compound that is within the scope of the claims of the '567 patent, the '567 patent is invalid as anticipated by the disclosure of Early et al.

Invalidity Based on Obviousness

In this example, Early's compound differs by only a single carbon atom. Thus, it does not anticipate the claimed compound, but under the Hass-Henze doctrine, a homolog of a known compound, differing by only a single carbon atom, is obvious over the known compound. Note, however, that there can be exceptions to this rule; for example, if the homolog has unexpected properties (e.g., better half-life, lower toxicity, and so forth), the claimed compound may not be obvious over the known compound.



Why Are FTO Analyses Conducted?

FTO analyses are conducted for a variety of reasons and by different parties. FTO analyses often occur prior to an investment in the Company. In this case, counsel for the investor may require an FTO analysis prior to closing the deal. An FTO analysis is frequently paid for by the Company; if the investment is made, it is not uncommon for the Company to reimburse the investor for the cost of the analysis.

It is also important to perform an FTO analysis prior to the acquisition of patent assets, such as an in-license or acquisition of a company or division. Particularly in the case of life sciences companies, the value of the patent assets is determined in large part by the ability to practice the claimed technology.

FTO analyses can also be used in “research tree decisions,” in which several potential research paths are technologically feasible. Generally, picking the path with the least third-party IP is desirable so as to avoid potential litigation or licensing royalties.

How Can FTO Analyses Help Avoid Common Mistakes of Emerging Growth Companies?

Getting an early jump on the issues associated with an FTO analysis can help your Company avoid a number of common mistakes during its lifetime. These mistakes can include:

- 1. Ignoring the competition’s portfolio.** Successful IP portfolio management obviously includes understanding the Company’s competitors in both technology and markets. In today’s competitive environment, it is crucial to also understand competitors’ IP portfolios and strategic IP plans to avoid present and future infringement.
- 2. Ensuring that your hiring practices protect your IP.** Many issues associated with employees are related to due-diligence evaluations. One area involved with the FTO process involves the contractual obligations of employees, which are frequently lateral hires from competitors. A company owns the intellectual output of its employees, as evidenced in its employment contracts. It should be noted that hiring foreign nationals raises some unique issues. Hiring former employees of a competitor without determining how the employee is legally required to handle confidential information can result in a number of issues. For example, if the employee is still under obligation to assign improvements of prior developed technology to a previous employer, the employee could potentially be compelled to assign to both former and current employers. Similarly, the Company should ensure that the employee does not divulge confidential information obtained from a previous employer.
- 3. Failing to obtain good title to IP.** Due to the fluidity of employee movement, it is crucial to obtain good title to all the Company’s IP. Resolving these issues and keeping good records regarding inventorship and employment obligations goes a long way. Several years

after a disgruntled employee leaves is not the time to ask for the assignment of valuable IP to the Company.

4. **Failing to conduct trademark searches.** Trademark searches and applications are reasonably straightforward and typically relatively inexpensive. Company names, potential product names, and so forth should all be searched prior to any public disclosure and before any serious investment.
5. **Failing to establish a trade secret program.** While trade secrets are less utilized in life sciences companies than in some other industries, it is important to both identify trade secrets and institute policies and procedures concerning the treatment of trade secret information and materials. Merely saying something is a trade secret is not sufficient. Establishing trade secret policies can be particularly problematic in life sciences settings, where results are often posted internally on bulletin boards and where lab meetings have handouts and slides.
6. **Failing to properly license technology.** Core technology is often in-licensed from universities or other companies. It is imperative to understand the scope of the grant of the license. The status of the license (e.g., exclusive or nonexclusive) is a starting point. Furthermore, the field of the grant must be broad enough to support the Company's end goals (e.g., the use of compound X within autoimmune diseases versus the use of compound X within rheumatoid arthritis, humans versus animals, research versus commercial uses). Similarly, limitations on territory (e.g., the United States versus the rest of the world) need to be understood; some companies may want to sell in the United States but make intermediate compounds for sale in China or India, for example.

A variety of other issues arise in the licensing arena, such as the rights of the federal government when inventions are developed using federal grants, sometimes referred to as "march-in rights." While different funding agencies (e.g., the National Institutes of Health, the National Science Foundation, the Department of Education, the Department of Defense) have different rules and rights, notification requirements are virtually universal. Your Company needs to ensure that the rules are followed in the lab receiving the grants and that it understands the potential limits of the use of the technology.

Similarly, your Company should evaluate licenses with regard to the rights to improvements, as generally companies want at least a right of first refusal over follow-on technologies developed in the original lab. License terms can also be an issue for purchased reagents, which in many cases carry a "for research use" only license. If raw materials or reagents that will be either converted to final products or used in kits, for example, are purchased under a "for research use" only license, problems may ensue.

Another issue that can arise is the control of the IP rights as well as the right to control the IP process at the United States Patent and Trademark Office (USPTO).

All of these issues will require that your Company either establish internal procedures with “go to” employees or outsource these functions. As is true for many issues in business, doing something right initially is generally far less expensive and problematic than trying to fix it later.

What Is an FTO Opinion?

A finding of infringement by a court will result in liability; a finding of “willful infringement” can have any damage award tripled. As a result, companies are interested in laying a trail that will support a finding of no willful infringement. Traditionally, one way that this is accomplished is to have “competent counsel” (usually patent counsel) draft an opinion that a company was either not infringing the claims of the patent or that the claims were invalid under any of the statutory requirements—usually referred to as an FTO opinion. In the recent *Knorr* case, the law associated with willful infringement was altered rather drastically.⁴ As a result, the presence of an FTO opinion is now only one of the factors that will be considered in the determination of willful infringement. However, the practice of having counsel (whether in-house or outside counsel) draft FTO opinions is still suggested in many cases.

It is important to note that having an FTO opinion will not prevent a company from being sued for infringement; rather, the sole purpose of an FTO opinion is to help prevent a finding of willful infringement and the possible corresponding tripling of damages.

In general, emerging companies need to understand the issues, know the problem areas, and have thought about possible solutions. For nascent technologies, rarely do investors require complete peace of mind. However, a company not knowing the competition’s IP and its potential effects can be embarrassing at best and expensive at worst.

Conclusion

Your Company should undertake the steps to identify third-party IP that could affect its freedom to make, use, or sell a proposed product or use its IP or a particular trademark. Such steps include searching for third-party patents, trademarks, and copyrights; using sound hiring practices; obtaining IP assignments of ownership; and obtaining legal opinions of noninfringement or invalidity. Such steps can add significant value to your Company as they allow your Company to create IP and mitigate or avoid possible risks.

Potentially dominating patents must be identified and their strength ascertained prior to introducing a new product to market. An apparently dominating patent can be removed as a substantial concern by a well-reasoned opinion of counsel that the patent is not infringed and/or invalid.

4. *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmBH v. Dana Corp.*, 383 F.3d 1337, 1341 (Fed. Cir. 2004).